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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,586	10/11/2001	Peter C. Meltzer	70207/48,913-CON	9855
21874	7590	01/23/2004	EXAMINER	
EDWARDS & ANGELL, LLP			AULAKH, CHARANJIT	
P.O. BOX 9169			ART UNIT	
BOSTON, MA 02209			PAPER NUMBER	

1625

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,586

Applicant(s)

MELTZER ET AL.

Examiner

Charanjit S. Aulakh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 22-27 are pending in the application.

Response to Arguments

2. Applicant's arguments filed on Dec. 1, 2003 with respect to claims 22-27 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 22-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicants have amended specification in the paper filed on Oct. 28, 2002 to claim priority to earlier applications. This is a new matter since the inventive entity is different in all those applications. Moreover, there is not even a single example of 3-alpha tropanes in the prior applications such as 09/875,523, now patent 6,670,375. The only exemplified 3-alpha isomers are of oxabicyclo octanes (see examples 15 and 16 in patent 6,670,375). Therefore, the applicants are not entitled to the earlier priority date of Nov. 3, 1995. The earlier priority date of the instant application is May 12, 1999 based on the provisional application.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 22-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-27 depend upon claim 22. In claim 22, the N in the formula needs to be substituted. The applicants mention that N8 is substituted with H or methyl. However, the applicants need to attach some variable to N such as A and then define A as H or methyl in order to overcome this indefiniteness rejection.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 22, 23 and 27 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kuhar (U.S. Patent no. 6,358,492).

Kuhar discloses dopamine transporter imaging ligand. The compounds disclosed in examples 2a, 2b, 2c, 2d and claim 1 of Kuhar clearly anticipate the compounds of instant claims when R1 represents COORa and Ra is methyl and R2 is a substituted phenyl group in the instant compounds of claim 22.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (U.S. Patent no. 3,813,404), Kuhar (U.S. Patent no.5,496,953), Davies (U.S. Patent no. 6,008,227) in view of Kuhar (U.S. Patent no. 6,358,492).

Clarke, Kuhar and Davies all disclose Tropane derivatives. The disclosed compounds of Clarke (see examples 1-14 and claims 1-8), Kuhar (see compounds RTI-183, RTI-218 and RTI-228 in table II) and Davies (see compounds in table I) differ from the instant compounds in having the instant R2 group as 3-beta isomer instead of 3-alpha isomer. However, Kuhar (U.S. Patent no. 6,358,492) teaches that 3-alpha isomers of several 3-beta (substituted phenyl) tropanes exhibit selectivity for dopamine transporter since their affinity for serotonin transporter is reduced (see col. 2, lines 14-27). Therefore, one skilled in the art would have been motivated to prepare the instant selective dopamine ligands (3-alpha isomers of tropane derivatives) by modifying non-selective dopamine and serotonin ligands (3-beta isomers of tropane derivatives) of Clarke, Kuhar and Davies since Kuhar teaches the selectivity of 3-alpha isomers for dopamine transporter over 3-beta isomers (see table 3).

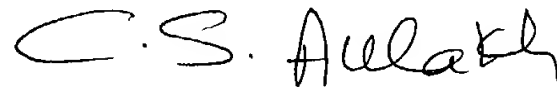
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

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(703)305-4482. The examiner can normally be reached on Monday through Thursday, 7:30 A.M. to 6:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.



Charanjit S. Aulakh
Primary Examiner
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